

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
14 October 2004 (14.10.2004)

PCT

(10) International Publication Number
WO 2004/087170 A1

(51) International Patent Classification⁷: **A61K 31/593**,
31/453, A61P 17/00, 1/00 // (A61K 31/593, 31:453)

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(21) International Application Number:
PCT/EP2004/003512

(22) International Filing Date: 2 April 2004 (02.04.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0307865.6 4 April 2003 (04.04.2003) GB

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- with amended claims

Date of publication of the amended claims: 25 November 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: COMBINATION OF A MACROLIDE T-CELL IMMUNOMODULATOR AND A CALCIFEROL FOR THE TREATMENT OF SKIN DISEASES OR OF INFLAMMATORY BOWEL DISEASE

(57) Abstract: Synergistic combinations of a macrolide T-cell immunomodulator or immunosuppressant such as 33-epichloro-33-desoxyascomycin and a calciferol such as calcipotriol or tacalcitol are provided, which are useful in particular in the treatment of dermatological diseases such as atopic dermatitis, acne and psoriasis, or of inflammatory bowel disease (IBD).

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AMENDED CLAIMS

[received by the International Bureau on 16 August 2004 (16.08.04);
original claims 1-5 replaced by amended claims 1-5]

1. A pharmaceutical composition comprising pimecrolimus in combination or association with a calciferol together with at least one pharmaceutically acceptable diluent or carrier.
2. A composition according to claim 1 wherein the calciferol is calcipotriol or tacalcitol.
3. A method of treatment of a dermatological disease such as atopic dermatitis, acne or psoriasis, or of inflammatory bowel disease (IBD), in a subject suffering from or at risk for such condition, comprising co-administering a synergistically effective amount of a composition according to claim 1.
4. A process for the preparation of a composition of claim 1 comprising mixing pimecrolimus and a calciferol in combination or association with at least one pharmaceutically acceptable diluent or carrier.
5. A kit of parts comprising pimecrolimus and a calciferol in separate unit dosage forms together with instructions for use.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2004/003512

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/593 A61K31/453 A61P17/00 A61P1/00
//(A61K31/593,31:453)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/18468 A (AMERICAN HOME PROD) 7 May 1998 (1998-05-07) page 8, lines 25-36; claims 1,4-6,8	1-5
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

1 June 2004

Date of mailing of the international search report

12.07.2004

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2004/003512

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2004/003512

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Although claim 3 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2004/003512

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